

III. REMARKS

A. Summary of the Office Action and Claim Status

The cover page of the March 8, 2005 office action indicates that claims 12-20 are pending and rejected. The office action (1) objects to the drawings and requires corrected drawings; (2) rejects claims 12-20 under the first paragraph of 35 USC 112; (3) rejects claims 12-20 under the second paragraph of 35 USC 112; (4) rejects claims 12-16, 19, and 20 under 35 USC 102(e) based upon USP 5,489,295 to Piplani et al. (hereinafter "Piplani"); (6) rejects claims 17 and 18 under 35 USC 103 based upon Piplani; and (7) rejects claims 12-20 for obviousness-type double patenting over claims 1-23 of USP 6,689,158, 1-20 of USP 6,582,458, and claims 1-10 of USP 5,782,904.

Claims 12-36 are pending.

Claims 12 and 20 are the independent claims.

This amendment presents new dependent claims 21-36.

B. Response to the Items Noted in the Office Action

1. Response to the Objections to the Drawings

The examiner objected to the drawings under 37 CFR 1.83(a), stating that:

The drawings must show every feature of the invention specified in the claims. Therefore, the bifurcated prosthesis defined in claim 13 must be shown or the feature(s) canceled from the claim(s). No new matter should be introduced.

[Office action mailed March 8, 2005 page 2 lines 3-7.]

In response, the applicant submits Figure 8 showing a perspective view of a bifurcated prosthesis, and amends the "Brief Description of the Drawings" section to refer to Figure 8.

2. Response to the Rejection of Claims 12-20 under the First Paragraph of 35 USC 112

The examiner rejected claims 12-20 under 35 USC 112, first paragraph, stating that:

Claims 12-20 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This application is described as a continuation of one of a series of parent applications. However, there is no basis in the original disclosure of the parent applications for the limitation in claim 12, “such that the plurality of apices extend across a lumen of the second vessel without occluding the lumen of the second vessel”. Also, there is no basis in the original disclosure of the parent applications for the limitation in claim 20, “and across the junction between the first vessel and the second vessel such that the prosthesis does not occlude a lumen of the second vessel”. [Office action mailed March 8, 2005 page 3 line 13 through page 4 line 4.]

In response, the applicant respectfully disagrees. The applicant explains below why each of the recitations of claims 12 and 20 on which the examiner based these rejections has 35 USC 112 first paragraph written description support in the specification.

- a. **The Recitation in Claim 12 “such that the plurality of apices extend across a lumen of the second vessel without occluding the lumen of the second vessel”**

Claim 12 recites:

12. (Original) A prosthesis for placement in a lumen of the first vessel that intersects with a second vessel, the prosthesis comprising:

- a first end,
- a second end, and

wherein at least one of the first and second ends is provided with a wire structure which has a plurality of apices extending beyond at least a portion of the corresponding end such that the plurality of apices extend across a lumen of the

second vessel without occluding the lumen of the second vessel.

The recitation identified by the examiner is part of the recitation of the last paragraph of claim 12. Since page 3 lines 13-16 of the specification provides express support for the recitation identified by the examiner, the applicant is not certain of the basis for the rejection. Therefore, the applicant discusses the last paragraph of claim 12, in toto, to ensure that the examiner and the applicant have the same understanding of support for that paragraph.

Claim 12 recites (1) a "first vessel that intersects with a second vessel" and (2) a prosthesis having (1) a "first end" and (2) a "second end." Thus, claim 12 provides useful antecedent for subsequently defining geometric relationships of either the first end or the second end of the prosthesis relative to the first vessel and the second vessel.

By definition, each vessel defines at least one lumen therein. Therefore, the recitation in claim 12 of "a lumen of the second vessel" is an inherent feature of the recited second vessel. Moreover, recitation of "a lumen" of the second vessel is supported by the disclosure throughout the specification of vessels having lumens. See for example the second paragraph of the specification (discussing lumens in which intraluminal grafts are intended to be inserted).

The specification also contains repeated references and substantial detail regarding the claimed "plurality of apices extending beyond" an end of a graft or prosthesis. See for example the first sentence of the "DISCLOSURE OF THE INVENTION" section, which states in pertinent part "one of the wires being located adjacent to one end of the graft body such that alternate *crests or apices of the wire projects beyond at least part of that end.*" Thus, the specification clearly discloses the claimed feature of a "plurality of apices extending beyond at least a portion of the corresponding end."

Finally, the specification also clearly discloses the claimed "plurality of apices extend across a lumen of the second vessel without occluding the lumen of the second vessel" at page 3 lines 13-16, which states that:

The wire crests may extend across the lumen of a vessel opening into the vessel in which the graft is being placed without occluding that lumen.

The recitation in the foregoing passage of "the lumen of a vessel opening into the vessel in which the graft is being placed" clearly discloses two connecting vessels; the vessel in which the graft is being placed, and another vessel. The recitation in the foregoing passage that "wire crests may extend across" clearly discloses the concept that wire crests or apices of a graft placed in a first vessel extending across the connecting lumen of the second vessel. The recitation in the foregoing passage that "the wire crests may extend across ... without occluding that lumen" clearly discloses the concept that the lumen of the second vessel is not occluded by the wire crests extended across it. Accordingly, the specification provides clear and unambiguous written description support for the recitation in claim 12 of "such that the plurality of apices extend across a lumen of the second vessel without occluding the lumen of the second vessel." Therefore, the rejection under the first paragraph of 35 USC 112 for lack of written description support in the specification based upon that recitation is improper and should be withdrawn.

Since claims 13-19 depend from claim 12, the rejections of claims 13-19 under the first paragraph of 35 USC 112 are also improper and should be withdrawn.

b. The Recitation in Claim 20 "and across the junction between the first vessel and the second vessel such that the prosthesis does not occlude a lumen of the second vessel"

Claim 20 recites:

20. (Original) A prosthesis for placement in a lumen of the first vessel that intersects with a second vessel, the prosthesis comprising:
a first end adapted for placement adjacent to a junction between the first vessel and the second vessel, and
a second end,
wherein the first end is reinforced with a wire member which has a plurality of apices extending beyond at least a portion of the first end and across

the junction between the first vessel and the second vessel such that the prosthesis does not occlude a lumen of the second vessel.

The recitation in claim 20 "and across the junction between the first vessel and the second vessel such that the prosthesis does not occlude a lumen of the second vessel" is supported by the specification for the same reasons stated above regarding the rejection of claim 12.

**3. Response to the Rejections of Claims 12-20 Under 35 USC 112,
Second Paragraph**

The examiner rejected claims 12-20 under 35 USC 112, second paragraph, stating that:

Claims 12-20 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how an object such as the claimed apices can extend across a lumen without, at least partially, occluding it. Therefore, it is unclear if the term "occluding" in claim 12 and "occlude" in claim 20 means only a total occlusion. If so, it appears to contradict the normal definition of these terms. [Office action mailed March 8, 2005 page 4 lines 5-13.]

In response, the applicant respectfully traverses the rejection because the claim recitation appears to be clear and definite and consistent with the dictionary definition of occlude. Occlude means to shut or close. See Attachment 1.¹ The applicant's claim 12 recitation that "the prosthesis does not occlude a lumen of the second vessel" is therefore literally accurate because claim 12's "... apices... extend[ing] across ... without occluding the lumen of the second vessel" do not shut or close the lumen of the second vessel. Similarly, claim 20's recitation of not

¹Attachment 1 is a printout of the definition of "occlude" per the On-line Medical Dictionary, Published at the Dept. of Medical Oncology, University of Newcastle upon Tyne Copyright 1997-2005.

occluding is also accurate, clear, and definite.

The examiner's opinion regarding claims 12 and 20 in reference to "occlude" is based upon a non sequitur. Partially occlude means partially shut or partially block. Whether the structures defined by claim 20 partially shut or partially block the lumen of the second vessel is irrelevant because that is not what the applicant claims. Therefore, the examiner's conclusion that claims 12 and 20 are indefinite because they do not recite partial occlusion is a non-sequitur. The applicant's claims recite (claim 12) a "plurality of apices extend across a lumen of the second vessel without occluding the lumen of the second vessel" and (claim 20) "the prosthesis does not occlude a lumen of the second vessel." Those recitations are consistent with the disclosure of wire apices extending across a lumen not closing or shutting the lumen, and therefore are accurate, clear, and definite.

Since the recitations of "without occluding" and "not occlude" are consistent with the teachings of the specification and the meaning of "occlude" claims 12 and 20 are not indefinite. Therefore, the rejections of claims 12 and 20 as indefinite are improper and should be withdrawn.

Claims 13-19 depend from claim 12 and are not indefinite for the same reasons applicable to claim 12.

4. Response to the Rejections of Claims 12-16, 19, and 20 Under Either 35 USC 102(e) or 35 USC 103(a) Based upon Piplani

a. Summary

Claims 12-16, 19, and 20 stand rejected under either 35 USC 102(e) or 35 USC 103(a) as being either anticipated or obvious over Piplani. In support of the rejections, the examiner stated that:

Claims 12-16, 19 and 20 are rejected under 35 USC 102(e) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Piplani et al. (5,489,295). As to claims 12 and 20, as best understood, Piplani et al., in figure 4, disclose prosthesis 20 wherein at least one of the first and second ends is provided with a wire structure (126 or 127) which has a plurality of apices (e.g. 132)

extending beyond at least a portion of the corresponding end. The apices are inherently capable of being located across a lumen of a second vessel.

Alternatively, it would have been obvious that the apices are capable of being located across a lumen of a second vessel. [Office action mailed March 8, 2005 page 5 lines 10-20.]

Claim 12 recites:

12. (Original) A prosthesis for placement in a lumen of the first vessel that intersects with a second vessel, the prosthesis comprising:

a first end,

a second end, and

wherein at least one of the first and second ends is provided with a wire structure which has a plurality of apices extending beyond at least a portion of the corresponding end such that the plurality of apices extend across a lumen of the second vessel without occluding the lumen of the second vessel.

In summary response, the applicant submits that Piplani does not disclose or suggest "A prosthesis for placement in a lumen of the first vessel that intersects with a second vessel" and an end having "apices ... extend[ed from an end of the graft] across a lumen of the second vessel," as recited in claim 12 and defined by claim 20. Specifically, Piplani does not disclose that the apices that extend from an end of the graft "extend across" the lumen of any vessel for which Piplani's graft is designed for the reasons presented below.

In addition, Piplani does not disclose features disclosed in this application and now claimed in newly presented dependent claims.

b. **Piplani Does Not Disclose “A prosthesis for placement in a lumen of the first vessel that intersects with a second vessel” and an end having “apices ... extend[ed from an end of the graft] across a lumen of the second vessel,” as Recited in Claim 12 and Defined by Claim 20**

The examiner admitted that Piplani does not expressly disclose that Piplani's springy sections 126, 127 extend across a lumen of any vessel. The examiner relied upon an inherency argument to conclude that Piplani's springy sections 126, 127 extend across a lumen of an intersecting vessel. However, Piplani does not inherently disclose a springy section extended across a lumen of an intersecting vessel for the following reasons.

Piplani discloses (see Figure 4) a bifurcated graft in which the bifurcation or crotch region is designed to span a patient's aorto-iliac arterial bifurcation. See the first sentence in Piplani's "Summary of the Invention" section at column 1 lines 21-27, which states "graft having a bifurcation ... *traversing* an aortic bifurcation...." Emphasis supplied. Moreover, Piplani discloses the springy sections 126, 127 are only at the ends of the graft, as is shown in Figure 4. Therefore, when installed in a patient, the springy sections 126, 127 do not extend across the lumens forming the aorto-iliac bifurcation because they are not adjacent the aorto-iliac bifurcation, and because each such springy section extends from the corresponding end of the graft away from the aorto-iliac bifurcation. Thus, springy section 126 resides in the abdominal aorta upstream of the aorto-iliac bifurcation and springy section 127 resides in an iliac artery below the aorto-iliac bifurcation. Obviously, Piplani's graft 20 was designed so that the graft's leg portions 116, 117 portion would extend over the aorto-iliac bifurcation, which means that the springy sections 126 and 127 did not overlap that bifurcation. In fact, that point is implied in Piplani's abstract (by the statement that the graft is "for repairing an aneurysm in the vicinity of an aortic bifurcation").

Consequently, it is not inherent in Piplani that Piplani's springy sections 126, 127 overlap a bifurcation in a vessel, and in fact Piplani discloses that they do not overlap such a bifurcation. Since Piplani springy sections 126, 127 are designed to not even overlap a region where a second vessel meets a first vessel, neither springy section 126, 127 at an end of Piplani's graft 20 can

extend across a second vessel. Therefore, Piplani does not inherently disclose "apices ...[of springy section 126 or 127] extend[ed from an end of the graft] across a lumen of the second vessel."

Therefore, the rejections of claims 12 and 20 are improper and should be reversed. Since claims 13-19 depend from claim 12, for the same reasons applicable to claim 12, the rejections of claims 13-19 are improper and should be reversed.

**c. Other Features not Disclosed in Piplani that are now Defined
in Newly Presented Dependent Claims**

Piplani discloses only self expanding spring structures (springy sections 126, 127) forming its apices. In contrast, this application discloses non springy structures. See the specification page 1 lines 12-14 and 22-24 (defining self expanding stents, which are stents based upon springy material); page 3 line 6 (disclosing graft including "malleable" wire); page 3 lines 3-6 (referring to the malleable nature and a permanent deformation, belling, of the wire apices); page 4 lines 33-35 (referring to the wire formed from stainless steel and malleable plastic, and not to spring steel or any other spring material); and page 9 lines 23-28 (wires are malleable, bendable, and not substantially resilient so that they have to be physically expanded into contact with the aorta "rather than expanding by virtue of their own resilience"). New dependent claims 21-24 relate to these disclosed differences.

Furthermore, Piplani's springy sections 126, 127 have a different morphology from the morphology of the wire strictures disclosed in this application. For example, Piplani discloses loops at the apices of its springy structures. See elements 133 (Figure 4) and 203 (Figure 8). Those loops are not generally sinusoidal or zig-zag in shape. This application at page 2 lines 7-8 discloses that the wires form "generally closed sinusoidal or zig-zag shape" and shows such shapes for example via Figure 3. New dependent claims 25-30 relate to those disclosed differences.

Still further, Piplani discloses springy sections only at ends of a graft. This application discloses wires arrayed along the length of the graft. See page 5 last line and the figures. New dependent claims 31-36 relate to those disclosed differences.

5. Response to the Rejections of Claims 17 and 18 Under 35 USC 103(a) Based Upon Piplani

Claims 17 and 18 stand rejected under 35 USC 103(a) as being obvious over Piplani. In support of the rejections, the examiner stated that:

Claims 17 and 18 are rejected under 35 USC 103(a) as being unpatentable over Piplani et al. (5,489,295). Piplani et al. fail to disclose stainless steel or plastic as the material for the wire structure. However, it is old and well known to use these materials in order to obtain the advantage of making the device biocompatible as well as strong. It would have been obvious to use either of these materials for the Piplani et al. wire structure so that it too would have these advantages. [Office action mailed March 8, 2005 page 5 lines 21-28.]

In response, the applicant submits that the examiner's reliance on official notice is improper. See Barry, "Did You Ever Notice? Official Notice in Rejections" 81 JPTOS 129 (1999).² Therefore, the rejections of claims 6, 8, 22, 37, 38, and 43 relying upon the official notice are improper and should be reversed. In addressing this topic, MPEP 2144.03(A) states that:

Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. As noted by the court in In re Ahlert, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing In re Knapp Monarch Co., 296 F.2d 230, 132 USPQ 6 (CCPA 1961)).

²Attachment 2 is a copy of Barry, "Did You Ever Notice? Official Notice in Rejections" 81 JPTOS 129 (1999).

By taking official notice, the examiner asserts that certain facts are well-known or are common knowledge in the art and are capable of instant and unquestionable demonstration. The applicants dispute these assertions because these facts are not capable of instant and unquestionable demonstration as being well-known. Therefore, in addition to the reasons applying to claims 12, the rejections of claims 17 and 18 are improper for this additional reason, and those rejections should be withdrawn.

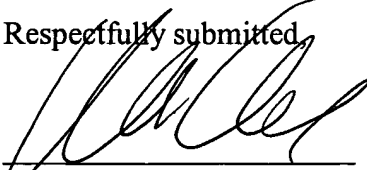
6. Response to the Rejections of Claims 12-20 for Obviousness-type Double Patenting Over Claims 1-23 of US Patent No. 6,689,158, Claims 1-20 of US Patent No. 6,582,458, and Claims 1-10 of US Patent No. 5,782,904

Claims 12-20 stand rejected under the judicially created doctrine of obvious-type double patenting. In support of the rejections, the examiner stated that:

Claims 12-20 are rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,689,158, claims 1-20 of U.S. Patent No. 6,582,458, and claims 1-10 of U.S. Patent No. 5,782,904. Although the conflicting claims are not identical, they are not patentably distinct from each other because the minor differences between the claims involve obvious differences. [Office action mailed March 8, 2005 page 6 lines 3-10.]

In response, the applicant submits herewith three terminal disclaimers, one terminal disclaimer over each one of USPs 6,689,158; 6,582,458; and 5,782,904 respectively.

7/5/2005
Date

Respectfully submitted,

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Printed: July 5, 2005 (11:09am)

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